

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2007/017120

International filing date (day/month/year)
31.07.2007

Priority date (day/month/year)
03.08.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/172 G06F19/00

Applicant
SMITHS MEDICAL MD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Ceccarelli, David

Telephone No. +49 89 2399-2653



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017120

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017120

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2-19,21-28,31-37,39-41,43-47,49-52</u>
	No: Claims	<u>1,20,29,30,38,42,48</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-52</u>
Industrial applicability (IA)	Yes: Claims	<u>1-52</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. The subject-matter of independent claims 1, 20, 29, 30, 38, 42, and 48 is not novel (Article 33(2) PCT) over the disclosure of document US2003/0163223 (D1) for example.
Said document D1 shows an apparatus for programming an infusion pump comprising a memory (RAM 116, ROM 118, figure 1), and a programmable circuit (microprocessor 102, figure 1) configured to generate several menus from which different items can be selected in sequence (see figures 3-27) and the corresponding method of programming as claimed in said claims.
2. Remaining claims 2-19, 21-28, 31-37, 39-41, 43-47 and 49-52 are at least not inventive (Article 33(3) PCT) when document D1 is considered as closest prior art. What to include in the choice of the different menus is a mere matter of design for the man skilled in the art of programming.
3. In general, it is believed that the present application merely discloses one of the many possible standard ways of programming an infusion pump as within the competence of a person skilled in the art and does not add anything inventive over the simple concept of a "programmable infusion pump" as such.
Therefore no matter in the whole application appears to potentially fulfil the requirements of Article 33(2) and (3) PCT.

Re Item VII

Certain defects in the international application

Document D1 is not cited in the description (Rule 5.1(a)(ii) PCT).
The independent claims are not drafted in the two-part form (Rule 6.3(b) PCT).
The claims do not contain any reference signs to the figures (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

The present application contains 7 independent claims with partly overlapping scope. Such way of claiming does not fulfil the requirements of Article 6 PCT regarding clarity and conciseness of the claims as a whole, since it is particularly cumbersome for a reader to clearly delimit the invention for which protection is sought. A single independent claim per category would have been appropriate in this respect.